

ADC® Satin™ Standard, Fiber Optic and Disposable Laryngoscope Blades and Handles



Directions
for Use



Thank you for choosing an ADC® Satin™ Laryngoscope.

Device Description and Intended Use

A Laryngoscope is a two-part, hand held device consisting of a handle that contains batteries and a detachable blade. Laryngoscopes are designed to provide illumination within the larynx during the process of performing intubations. This instruction book covers both standard, fiberoptic type and disposable laryngoscopes. Fiberoptic Laryngoscopes are indicated by an F following the item number / Disposables are indicated by a D following the item number.

Contraindications

The following are only relative contraindication to tracheal intubation:

1. Severe airway trauma or obstruction that does not permit safe passage of an endotracheal tube. Emergency cricothyrotomy is indicated in such cases.
2. Cervical spine injury, in which the need for complete immobilization of the cervical spine makes endotracheal intubation difficult.

General Warnings

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately could lead to patient injury, illness, or death.

WARNING: Federal law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.

WARNING: ONLY TRAINED PERSONNEL SHOULD USE A LARYNGOSCOPE FOR INTUBATION

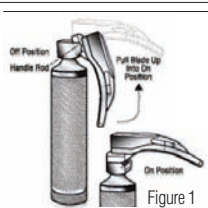
WARNING: ADC® recommends that spare lamps, batteries, and replacement parts always be available for emergency use.

WARNING: The sterilization guidelines included in this instruction booklet, provided by American Diagnostic Corp. (ADC®), are intended as procedures compatible with specific materials. Sterilization must be performed to approved hospital protocol. ADC® cannot guarantee that any of the recommended methods will guarantee sterility. This must be validated by the hospital and/or sterilization equipment manufacturer.

WARNING: Fiberoptic handles may be used with ALL fiberoptic blades (reusable or disposable) that conform to the ISO 7376-1 and ISO 7376-3 standards. Standard handles may be used with any standard blades that conform to the ISO 7376-1 and ISO 7376-2 standards. Standard and fiberoptic blades and handles are NOT interchangeable.

Operation of all Laryngoscope Models

To Activate: Attach selected blade onto handle by hooking blade onto handle rod as shown in Figure 1. Pull blade upward to open position to automatically activate light. To turn off, push blade downward into off position and disconnect from handle. (See Figure 1).



Compatibility/Standards

Standard ADC® Satin™ Laryngoscopes conform to current ASTM F965, ISO 7376-1, and ISO 7376-

2 standards. They are compatible with virtually all major brands of standard illumination hook on blades and handles.

Fiber optic ADC® Satin™ Laryngoscopes and Disposable Laryngoscope blades conform to current ASTM F1195, ISO 7376-1, and ISO 7376-3 standards. They are compatible with virtually all major brands of fiber optic illumination hook on blades and handles. For easy visual identification, ALL Fiber Optic models are clearly delineated by a green indicator on both handle and blade.

Cleaning, Disinfecting, and Sterilization Procedures

ADC® Satin™ Laryngoscope blades are crafted from rugged stainless steel. ADC® Disposable Fiberoptic Laryngoscope blades are crafted from poly-carbonate, and are for single use only and should not be cleaned or sterilized. Reusable handles are machined from chrome-plated brass or anodized aluminum. To ensure maximum life and optimum performance, the following instructions should be strictly adhered to. Disposable handles are made of ABS, and are for single use only and should not be cleaned or sterilized.

Cleaning Procedure (all reusable models): Almost immediately after use, Laryngoscope Blades should be cleaned to prevent blood, saliva etc. residues from drying. On Conventional blades, the lamp socket and wires are an integral part of the blade for cleaning and replacement.

WARNING: Ultrasonic cleaning is not recommended.

Disinfection/Sterilization Warnings for All Laryngoscope Blades

CAUTION: ADC® laryngoscope blades do not come sterilized. The Sterrad process is NOT to be used with disposable fiberoptic blades or fiberoptic blades.

WARNING: Flash autoclaving and hot air sterilization are not recommended, these processes will damage the instrument. The repeated high temperature and changes in temperature caused by autoclaving will shorten the life of all laryngoscope products.

WARNING: Do not immerse blades in Bleach, Betadine, or peroxide solutions. Doing so will severely damage the instrument. Also, avoid metal to metal contact on non-disposable blades.

Disinfection/Sterilization Warnings for All Battery Handles:

CAUTION: Do not allow excess fluid to seep into electrical contact. Be sure that the top and bottom of the battery handle are secure before use. Poor maintenance of this device or failure to follow the warnings in this instruction booklet could result in device failure and/or patient injury.

Repair/Maintenance

Battery Replacement: (Reuseable Models)

- 1) Unscrew bottom portion of handle and remove batteries.
- 2) Alkaline batteries should be used with your handle for maximum performance and are recommended for replacement. Ordinary carbon zinc batteries may also be used.
- 3) Replace with appropriate size battery, taking care to insert positive end first. On stubby handle, insert one battery with negative end against screw and insert second battery with positive end in first (See Figure 2).

Lamp Replacement: (Standard Models)

For correct illumination, alignment, and assurance of watertight seal during immer-

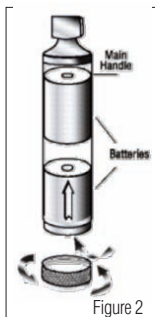


Figure 2

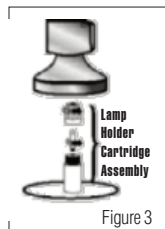
sion/autoclave, we recommend using only ADC #4500-1 and #4501-1 replacement lamps for standard blades.

- 1) To remove lamp on standard blades, grip lamp collar and rotate lamp counterclockwise until free.
- 2) Replace the lamp with a new ADC lamp.
- 3) Verify that lamp is sufficiently tightened before use.

CAUTION: Be sure lamp's glass surface is clean and free from fingerprints after assembly. If necessary, the glass may be cleaned with a soft cloth or cotton ball moistened in alcohol.

Lamp Replacement: (Fiberoptic Models) For correct illumination and alignment we recommend using only ADC replacement lamp model #4532-1 (See Figure 3).

- 1) Prior to removal, allow lamp time to cool.
- 2) Unscrew the laryngoscope head from the barrel of the handle in a counterclockwise direction. Cartridge (lamp holder) will remain in head (top portion of handle).
- 3) Unscrew the cartridge from the head in a counterclockwise direction.
- 4) Unscrew the plastic shroud from the cartridge in a counterclockwise direction.
- 5) Unscrew the lamp in a counterclockwise direction.
- 6) Replace the ADC® lamp and tighten it sufficiently.
- 7) Replace the plastic shroud and screw the cartridge back onto the head.
- 8) Screw the head back on the barrel of the handle.



CAUTION: Be sure lamp's glass surface is clean and free from fingerprints after assembly. If necessary, the glass may be cleaned with a soft cloth or cotton ball moistened in alcohol.

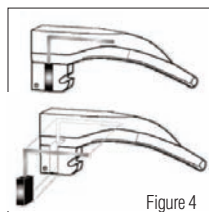
Fiber Optic Light Guide Replacement

- 1) Loosen the locking screw with a screwdriver. (Note: This screw is NOT designed to be completely removed.

This prevents the screw from falling out while the laryngoscope is in use. DO NOT attempt to remove this screw from the laryngoscope blade.)

- 2) Pull out the green base of the fiberoptic bundle and slide out the light guide (See Figure 4). (Note: The fiberoptic bundle is tightly fitted and may be difficult to remove.)

- 3) Insert new fiberoptic bundle by reversing the above steps.
- 4) Tighten the locking screw, ensuring that the fiberoptic bundle is securely attached to the laryngoscope blade.



Test Procedures

Laryngoscope blades and handles should always be tested after cleaning/disinfecting/sterilization, and prior to use. To test, connect the laryngoscope blade to handle and push blade to ON position. If the unit fails to light or flickers, check the lamp for a secure connection, batteries, and electrical contacts. Be sure to have adequate supplies of replacement bulbs and batteries.

Caps on battery handle should be secure before use. If they are not, it could cause the blade to move out of position. Laryngoscopes should be visually inspected for wear or aging prior to use and after long storage periods. It is strongly recommended that back-up laryngoscopes are

kept on hand for emergency situations.

Basic Cleaning Procedure for Standard and Fiberoptic Blades

Prepare a Klenzyme®, Manu-klenz™, or equivalent cleaning solution as per manufacturer's instructions and soak for ten minutes. Rinse devices with lukewarm running tap water for one minute to remove any residual detergent after cleaning. Dry with a clean, lint-free cloth. Note: Always allow blades to completely dry before disinfection or use.

Basic Cleaning Procedures for Standard and Fiberoptic Handles

Prepare a Klenzyme®, Manu-klenz™, or equivalent cleaning solution as per manufacturer's instructions. Remove both end caps from device and rinse with lukewarm tap water until all visible contamination has been removed. Soak handle and end caps in the prepared solution for a minimum of ten minutes, ensuring that all components are fully submerged. After the soak, the components should be scrubbed with a soft bristled brush paying particular attention to hard to reach areas. Rinse with cool running tap water to remove all residual detergent. Dry with a clean, lint free cloth. Note: Always allow handles to completely dry before disinfection or use.

High Level Disinfection for Standard and Fiberoptic Blades

To achieve high level disinfection, a 2.4% glutaraldehyde solution (Cidex® or equivalent) must be prepared at 77°F (25°C) to the manufacturer's instructions. The blades should be fully immersed in the disinfectant for a minimum of 45 minutes. No air bubbles should be visible on the immersed blades during this soak time. The blades should then be removed from the disinfectant and immersed in purified water to rinse off all disinfectant. Immersion should be for a minimum of one minute and the process should be repeated two additional times using fresh purified water each time. Once rinsing is complete, the blades should be thoroughly dried using a sterile, lint-free cloth. Note: Always allow blades to completely dry before use.

High Level Disinfection for Disposable Fiberoptic Blades

Disposable fiberoptic laryngoscope blades are supplied non-sterile. They are designed for single patient use only and are not disinfected after use. Gas sterilization by Ethylene oxide following these guidelines. Temperature 55°C (±5°C) EO pressure - 180 mmHg (± 20 mmHg) Chamber pressure 210mmHg (±20mmHg).

High Level Disinfection for Standard and Fiberoptic Handles

To achieve high level disinfection, a 2.4% glutaraldehyde solution (Cidex® or equivalent) must be prepared at 77°F (25°C) to the manufacturer's instructions. The end caps of the handles must be removed and both the end caps and handles should be fully immersed in the disinfectant for a minimum of 45 minutes. No air bubbles should be visible on the immersed components during this soak time. The components should then be removed from the disinfectant and immersed in purified water to rinse off all disinfectant. Immersion should be for a minimum of one minute and the process should be repeated two additional times using fresh purified water each time. Once rinsing is complete, the components should be thoroughly dried using a sterile, lint-free cloth. Note: Always allow components to completely dry before reassembling the handles, inserting batteries, or using the devices.

Steam Sterilization for Standard and Fiberoptic Blades and Handles

Sterilizer Type:	Prevacuum	Sterilizer Type:	Gravity
Preconditioning Pulses:	3	Minimum Temperature:	249.8°F
Minimum Temperature:	269.6°F (132°C)		(121°C)
Full Cycle Time:	4 minutes	Full Cycle Time:	30 minutes
Minimum Dry Time:	20 minutes	Minimum Dry Time:	15 minutes

LIMITED WARRANTY

American Diagnostic Corporation (ADC®) warrants its products against defects in materials and workmanship under normal use and service as follows:

1. Warranty service extends to the original retail purchaser only and commences with the date of delivery.
2. Your Laryngoscope is warranted for one year from date of purchase (all parts).

What is Covered: Replacement of parts, and labor.

What is Not Covered: Transportation charges to and from ADC®. Damages caused by abuse, misuse, accident, or negligence. Incidental, special, or consequential damages. Some states do not allow the exclusion or limitation of incidental, special, or consequential damages, so this limitation may not apply to you.

To Obtain Warranty Service: Send item(s) postage paid to ADC®, Attn: Repair Dept., 55 Commerce Dr., Hauppauge, NY 11788. Please include your name and address, phone no., proof of purchase, and a brief note explaining the problem.

Implied Warranty: Any implied warranty shall be limited in duration to the terms of this warranty and in no case beyond the original selling price (except where prohibited by law). This warranty gives you specific legal rights and you may have other rights which vary from state to state.

REPLACEMENT PARTS CHART

DESCRIPTIONS	STANDARD MODELS		FIBEROPTIC MODELS			SPU MODELS
Laryngoscope Item	Standard Blade	Standard Replacement Lamp	Fiberoptic Blade	Fiberoptic Replacement Lamp	Fiberoptic Light Guide	SPU Blade
Mac 0	4070	4500	4070F	N/A	4070FLP-00	N/A
Mac 1	4071	4500	4071F	N/A	4071FLP-00	4071D-20
Mac 2	4072	4500	4072F	N/A	4072FLP-00	4072D-20
Mac 3	4073	4501	4073F	N/A	4073FLP-00	4073D-20
Mac 4	4074	4501	4074F	N/A	4074FLP-00	4074D-20
Miller 00	4080-0	4500	N/A	N/A	N/A	4080-0D-20
Miller 0	4080	4500	4080F	N/A	4080FLP-00	4080D-20
Miller 1	4081	4500	4081F	N/A	4081FLP-00	4081D-20
Miller 2	4082	4501	4082F	N/A	4082FLP-00	4082D-20
Miller 3	4083	4501	4083F	N/A	4083FLP-00	4083D-20
Miller 4	4084	4501	4084F	N/A	4084FLP-00	4084D-20
Wisconsin 0	4090	4500	N/A	N/A	N/A	N/A
Wisconsin 1	4091	4500	N/A	N/A	N/A	N/A
Wisconsin 1.5	40915	4500	N/A	N/A	N/A	N/A
Wisconsin 2	4092	4501	N/A	N/A	N/A	N/A
Wisconsin 3	4093	4501	N/A	N/A	N/A	N/A
Wisconsin 4	4094	4501	N/A	N/A	N/A	N/A
"C" Cell Handle	4065	N/A	4065F	4532	N/A	4065D-20
"AA" Cell Handle	4066	N/A	4066F	4532	N/A	N/A
Stubby Handle	4067	N/A	4067F	4532	N/A	N/A



ADC
55 Commerce Drive
Hauppauge, NY 11788
U.S.A.



ADC (UK) Ltd.
Unit 6, PO14 1TH
United Kingdom

Inspected in the U.S.A.
Made in China
tel: 631-273-9600, 1-800-232-2670
fax: 631-273-9659

www.adctoday.com
email: info@adctoday.com